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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/542,445	04/04/2000	Mark A. Staples	BEH-7354A-Div	5919

34500 7590 07/08/2003

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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 07/08/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/542,445

Applicant(s)

Staples et al.

Examiner

S. Devi, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 21, 2003
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

- 1) Acknowledgment is made of Applicants' amendment filed 04/21/03 (paper no. 18) is response to the non-final Office Action mailed 12/31/02 (paper no. 16). With this, Applicants have amended the specification.

Status of Claims

- 2) No claims have been amended via the amendment filed 04/21/03.
Claims 1-3 are pending and are under examination.

Prior Citation of Title 35 Sections

- 3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

- 4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Maintained

- 5) The objection to the specification made in paragraph 7(b) of the Office Action mailed 09/04/01 (paper no. 9) is maintained for reasons set forth therein. Applicants have requested previously that amendments to the trademark recitations be done via an Examiner's amendment after the indication allowable subject matter.

Objection(s) Withdrawn

- 6) The objection to the abstract of the specification in the paragraph 6 of the Office Action mailed 12/31/02 (paper no. 16) is withdrawn in light of Applicants' amendment to abstract.

Rejection(s) Maintained

- 7) The rejection of claims 1-3 made in paragraph 8(a) of the Office Action mailed 09/04/01 (paper no. 9) under the judicially created doctrine of obviousness-type double patenting over claims 1-4 of the US patent 6,171,801, is maintained for reasons set forth therein. Applicants have assured the Office that they will file a terminal disclaimer once the claimed deemed allowable.
- 8) The rejection of claims 1-3 made in paragraph 8(b) of the Office Action mailed 09/04/01

(paper no. 9) under the judicially created doctrine of obviousness-type double patenting over claims 1, 2, 4, 5, 10, 11, 26 and 27 of the patent, US 6,159,698, is maintained for reasons set forth therein. Applicants have assured the Office that they will file a terminal disclaimer once the claims are deemed allowable.

9) The rejection of claims 1-3 made in paragraph 10 of the Office Action mailed 12/31/02 (paper no. 16) under 35 U.S.C § 103(a) as being unpatentable over Tabachnick *et al.* (*Arch. Biochem. Biophys.* 136: 467-479, 1970) in view of Khanna *et al.* (US 4,798,804, already of record), is maintained for reasons set forth therein and herebelow.

Applicants contend that Tabachnick *et al.* teach that *ortho* substituted benzoic acid derivatives do not work to displace thyroxine from albumin. Tabachnick's abstract is stated to teach that bulky halogen atoms *ortho* to the carboxylate group caused large reductions in relative binding affinities to benzoates. Applicants point to Table II and state that Tabachnick *et al.* teach that alkyl substituents are least preferred. Applicants conclude that Tabachnick *et al.* teach away from Applicants' method. Applicants submit that one skilled in the art would not look to Khanna for a specific releasing agent that is an *ortho* substituent, and that Khanna does not teach or suggest a method to release a ligand from an endogenous protein.

Applicants' arguments have been carefully considered, but are non-persuasive. It should be noted that only claim 2 is limited to the use of the compound where X is O. Tabachnick *et al.* taught the relative affinities of substituted benzoates for HSA. In the abstract or in Table II, Tabachnick *et al.* did not teach the total absence of affinity of substituted benzoates for HSA. Instead, Tabachnick *et al.* demonstrated that *ortho* substituent shows much better affinity for HSA compared to benzoate and 2, 5 substituted benzoate, and almost the same affinity for HSA as that shown by 2,6-substituted benzoate. Since a reduction in relative affinity is not equivalent to absence of affinity, Tabachnick *et al.* does not teach away from the claimed invention, but teach the *ortho* substituted benzoate as one of the releasing agents. Moreover, the fact that seventeen years after Tabachnick's disclosure, as opposed to getting discouraged from Tabachnick's teachings, Khanna *et al.* expressly taught the successful use of the specific substituted benzoic acid, methoxybenzoic acid, as a releasing agent for releasing a ligand from a complex, is *prima facie* evidence that Tabachnick *et al.* do not teach away from the instant invention. Since the primary reference, Tabachnick *et al.*, already taught the use of

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an *ortho* substituted benzoic acid derivative in a method for releasing or displacing thyroxine (i.e., a ligand) specifically from a complex with human serum albumin (i.e., endogenous protein) by contacting a medium containing the complex with an effective amount of a substituted, or *ortho* substituted benzoic acid derivative, Khanna does not have to teach or suggest a method to release a ligand from an endogenous protein. The rejection stands.

Remarks

- 10) Claims 1-3 stand rejected.
- 11) Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

- 12) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242, which is able to receive transmissions 24 hours a day and 7 days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

- 13) Any inquiry concerning this communication or earlier communication(s) from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail service. The Examiner can normally be reached on Monday to Friday from 7.15 a.m to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

July, 2003


S. DEVI, PH.D.
PRIMARY EXAMINER